Tytan Medical Corp.

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Website:www.tytan.com.tw

" 510(k) Summary "

JAN 1 4 2010

K092893

Submitter's Name:	**TYTAN Medical Corp.**
Address:	*6F-4, No. 11, Wu-Chun 1 Road, Hsin Chuang, Taipei, 24892, Taiwan, ROC*
Telephone:	886-2-22989579
FAX:	886-2-22989578
Contact Person:	Dr. Jen, Ke-Min
Date Summary Prepared:	August 30, 2008
Proprietary Name:	TYTAN Automatic Aneroid Sphygmomanometer model A730 and TYTAN Manual Digital LCD Sphygmomanometer model A830
Common Name:	BLOOD PRESSURE MONITOR
Classification Name:	NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM (per 21CFR section 870.1130)
Device Class:	Class II (performance standards)
Specialty:	CARDIOVASCULAR
Product code:	DXN
Legally Marketed (Predicate) Device :	*TYTAN Professional / Economy Series Sphygmomanometer 710, 700 (K033025);* *A & D Medical UM-101 Digital Blood Pressure Monitor(K061456)*

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Description of the new device: (Same as the predicate devices)

TYTAN Automatic Aneroid Sphygmomanometer A730 and TYTAN Manual Digital LCD Sphygmomanometer A830 series use the Auscultatory method to measure the blood pressure. It needs to use the stethoscope as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of TYTAN Automatic Aneroid Sphygmomanometer A730 and TYTAN Manual Digital LCD Sphygmomanometer A830 series are substantially equivalent to TYTAN Professional / Economy Series Sphygmomanometer 710, 700 (K033025) and A&D Medical UM-101 Digital Blood Pressure Monitor(K061456). There are the same design specifications, the same form and intended to be used in the same manner that means the new devices are same as the predicate devices.

The mainly different are:

1. The new devices TYTAN A730 can use the Li-ion battery and AC adapter to recharge the electric power, but the predicate devices TYTAN 710 / 700 (K033025) have not the power capability.
2. The new devices TYTAN A730 and A830 series can not display the pulse information but the predicate device A&D Medical UM-101 Digital Blood Pressure Monitor (K061456) has numerical pulse display.

Thus there are substantially equivalent.

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Test Summary:

1. **ELECTRIC SAFETY, EMC and FCC test reports,**

General safety	*IEC 60601-1:1988+ A1:1991+ A2:1995*	***PASS***
	EN 60601-1:1990+ A1:1993+ A2:1995+ A13:1996	***PASS***
EMC conformity	*EN 60601-1-2: 2001+ A1:2006*	***PASS***

2. **WOVEN COTTON SHEETING:** (Same as the predicate devices TYTAN 710/700)

   Uses the 510K Blood-Pressure Cuff: TYTAN Blood-Pressure Cuff (K051539).

3. **PERFORMANCE & CLINICAL TEST**
   AAMI / ANSI SP10:2002

TYTAN Medical Corp. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.

Dr. Jen, Ke-Min
Official Correspondent
TYTAN Medical Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 23 2010

Tytan Medical Corp.
c/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-Chu City
CHINA (TAIWAN) 30067

Re: K092893
Trade Name: Tytan Automatic Aneroid Sphygmomanometer, Model A730; and, Tytan Digital LCD Sphygmomanometer, Model A830
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: December 18, 2009
Received: December 28, 2009

Dear Dr. Jen :

This letter corrects our substantially equivalent letter of January 14, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

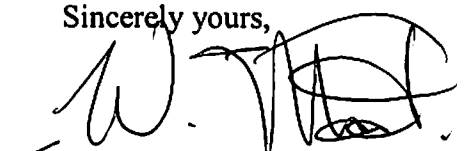
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K092893

Device Name: TYTAN Medical Corp.
TYTAN Automatic Aneroid Sphygmomanometer model A730 and
TYTAN Manual Digital LCD Sphygmomanometer model A830

- ***Indications for use:***

The TYTAN Automatic Aneroid Sphygmomanometer model A730 and TYTAN Manual Digital LCD Sphygmomanometer model A830 are noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressures, at hospital or professional environment by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092893